Remarks:

Claims 1-18 are in the case. During a telephone conversation on August 9, 2004, Applicant made a provisional election with traverse to prosecute the invention of Group I, drawn to a pharmaceutical composition comprising albumin and polyunsaturated fatty acid, classified in Class 514, subclass 12, of which claims 1-7 are readable thereupon. Applicant affirms this election and withdraws claims 8-18 from consideration. Claims 1 and 2 have been amended to overcome the Examiner's rejections. In addition, withdrawn claim 8 has also been amended. No new matter has been added by the amendments to the claims. The Examiner's rejections are respectfully traversed and reconsideration of the rejections is hereby requested.

Examiner's Rejection of Claims 1-2 and 5-7 Under 35 U.S.C. § 102

Claims 1-2 and 5-7 stand rejected under 35 USC § 102(b) as being anticipated by Wong et al, an article entitled "Inhibition of Apolipoprotein Secretion and Phosphatidate Phosphohydrolase Activity by Eicosapentaenoic and Docosahexaenoic Acids in the Perfused Rat Liver." The pharmaceutical compositions of claims 1 and 2 have been amended to include the element of a therapeutically effective amount of albumin and polyunsaturated fatty acid for mitigating ischemic and hemorrhagic tissue damage, as well as a pharmaceutically suitable carrier. The Applicants respectfully submit that the Wong et al. reference does not disclose these elements. Furthermore, the Applicants further submit that the Wong et al. reference is not an enabling disclosure.

An anticipating reference "requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Further, "under 35 U.S.C. § 102, anticipation requires

that...the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

The Wong et al. reference discusses the effects of acute infusion of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), compared to oleic acid (OA), on the secretion of newly synthesized apolipoproteins in the liver and the decrease in phosphatidate phosphohydrolase (PPH) activity in the cytosol and microsome fractions of the liver. *See* Wong et al., pg. 1180. One of the purposes of the study was to determine whether the decreased triacylglycerol (TAG) output observed in feeding studies, wherein rats were fed diets rich in DHA and EPA, was also demonstrable in short-term infusions of DHA and EPA. *See* Wong et al., pg. 1177.

The Examiner states that Wong et al. discloses **therapeutic** compositions comprising albumin bound to DHA, citing tables 1-4 appearing on pages 1178-79. The Applicants respectfully submit that Wong et al. does not disclose pharmaceutical compositions comprising a therapeutically effective amount of albumin and DHA for the mitigation of ischemic and hemorrhagic tissue damage.

The material used in the experiments discussed in Wong et al. cannot be considered therapeutic. The material was not administered to a living organism for the treatment of any discernable malady. Rather, male Sprague-Dawley rats were euthanized and their livers were excised and perfused with a solution of fatty acid and albumin having a 5:1 molar ratio in order to simulate the effect on the liver of a DHA/EPA-rich diet. *See* Wong et al., pg. 1177.

Furthermore, according to the paragraph entitled "Materials and Methods," the solution employed in the liver perfusion experiment appears to be simply a mixture of "fatty acid-poor

bovine serum albumin" and a relatively pure fatty acid, either OA, DHA, or EPA. Wong et al. does not disclose any procedure for loading albumin with a specific concentration of fatty acid, rather the reference describes a solution having a 5:1 molar ratio of fatty acid to albumin and maintaining a free fatty acid concentration. The chemical structure of albumin is well known in the art. Based on the number of binding sites, the upper limit of bound fatty acids is approximately 4 mole/mole of albumin. By simply mixing 5 moles of relatively pure fatty acid with fatty-acid poor bovine serum albumin, one could ensure the maintenance of a free fatty acid concentration.

In addition, the Applicants submit that Wong et al. is not enabling, thus cannot be used to support the Examiner's rejection. As stated above, the reference does not disclose any procedure for loading albumin with a specific concentration of fatty acid nor does it disclose any therapeutic dosages for any condition whatsoever. Claims 1 and 2 of the instant application both comprise a therapeutically effective amount of albumin and polyunsaturated fatty acid for treating ischemic and hemorrhagic tissue damage, which is defined in the specification at pg. 7, lines 7-12. It cannot be said that Wong et al. enables one of ordinary skill in the art to make and use the invention by disclosing the uptake of fatty acid upon the perfusion of dead rat livers.

Based upon the foregoing, the Applicants submit that Wong et al. does not disclose a therapeutically effective amount of albumin and polyunsaturated fatty acid for mitigating ischemic and hemorrhagic tissue damage, and that claims 1 and 2 are now in a condition for allowance. As claims 5-7 are dependent either directly or indirectly from claims 1 or 2, the Applicants submit that they too are now in condition for allowance.

Examiner's Rejection of Claims 2-4 Under 35 U.S.C. § 103

Claims 2-4 stand rejected under 35 USC § 103(a) as being unpatentable over Wong et al. in view of Crespo et al., US Patent No. 6,248,588. The Applicants believe that the Examiner intended to reject claims 3-4, rather than 2-4 since claim 2 does not recite either human serum albumin or recombinant human albumin.

In either case and for the reasons detailed above, the Applicants respectfully submit that Wong et al. and Crespo et al. do not disclose all of the elements of neither independent claim 2 nor dependent claims 3 and 4.

Of relevance to the instant application, Crespo et al. discloses the interchangeability between human serum albumin and recombinant human albumin. Crespo et al. does not disclose pharmaceutical compositions comprising a therapeutically effective amount of albumin and DHA for the mitigation of ischemic and hemorrhagic tissue damage.

As stated above, Wong et al. neither discloses pharmaceutical compositions comprising a therapeutically effective amount of albumin and DHA for the mitigation of ischemic and hemorrhagic tissue damage nor does it enable one of ordinary skill in the art to make and use the invention. Since neither of the references relied on by the Examiner contain all of the elements of claims 2-4, the Applicants respectfully submit that the claims are in condition for allowance.

Conclusion

In view of the foregoing remarks, the Applicants request the Examiner withdraws the 35 USC §§ 102 and 103 claim rejections. It is respectfully submitted that this application is now in condition for allowance. Further, Applicants request that the Examiner rejoin the withdrawn claims.

Respectfully submitted,

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